

# EXHIBIT B

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

STEVEN W. SAMPSON, TRUSTEE,

Plaintiff,

- against -

JAMES D. ROBINSON III, LEWIS B.  
CAMPBELL, JAMES M. CORNELIUS,  
LAURIE H. GLIMCHER, M.D., VICKI L.  
SATO, PH.D., LEIF JOHANSSON, LOUIS  
J. FREEH, MICHAEL GROBSTEIN, and R.  
SANDERS WILLIAMS, M.D.,

Defendants,

and

BRISTOL-MYERS SQUIBB COMPANY,

Nominal Defendant.

Case No. 1:07-CV-06890-PAC

Related Case No. 1:07-cv-05867-PAC

**AMENDED VERIFIED  
SHAREHOLDER  
DERIVATIVE COMPLAINT**

Plaintiff Steven W. Sampson, Trustee, by and through his attorneys, derivatively on behalf of Bristol-Myers Squibb Company ("Bristol-Myers" or the "Company"), alleges upon personal knowledge as to himself and his own acts, and upon information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through his attorneys, which included, a review of Securities and Exchange Commission ("SEC") filings, news reports, press releases, the May 30, 2007 Felony Information filed by the Antitrust Division of the United States Department of Justice ("DOJ") in the United States District Court for the District of Columbia (Criminal No.: 07-140 (RMU)), the May 31, 2007 Plea Agreement between the DOJ and Bristol-Myers filed in United States District Court for the District of Columbia (Criminal No.: 07-140 (RMU)), and other publicly available documents regarding Bristol-Myers, as follows:

### SUMMARY OF THE ACTION

1. This is a shareholders' derivative action brought on behalf of Nominal Defendant Bristol-Myers against its Board of Directors James D. Robinson III, Lewis B. Campbell, James M. Cornelius, Laurie H. Glimcher, M.D., Vicki L. Sato, Ph.D., Leif Johansson, Louis J. Freeh, Michael Grobstein, and R. Sanders Williams, M.D. (collectively, "Director Defendants"), seeking to remedy Director Defendants' breaches of fiduciary duties and other violations of law.

2. This shareholders' derivative action seeks redress for the harm caused to the Company (economic and otherwise) arising out of Director Defendants' unlawful actions and/or inactions relating to the illegal agreement whereby Bristol-Myers and France's Sanofi-Aventis ("Sanofi"), the third largest pharmaceutical drug company in the world, (1) agreed to pay Apotex Corporation ("Apotex"), a subsidiary of Apotex, Inc., a closely-held company and Canada's largest generic drug manufacturer, not to market a generic version of Bristol-Myers' blockbuster brand-name prescription drug, Plavix; (2) agreed to forego a valuable right to collect treble damages in a patent suit against Apotex in which Bristol-Myers ultimately prevailed; and (3) agreed to permit Apotex temporarily to flood the market with a generic version of Plavix, which cost Bristol-Myers more than \$1 billion in Plavix sales.

3. Plavix gained approval from the Food and Drug Administration ("FDA") on November 17, 1997, and is currently protected by at least one United States patent through 2011. Jointly marketed by Bristol-Myers and Sanofi, Plavix is a brand name prescription drug that inhibits platelets in the blood from clotting, which reduces the risk of heart attack, stroke or vascular-related death. Bristol-Myers began selling Plavix throughout the United States pursuant to its business partnership with Sanofi. Plavix is the world's second best-selling drug, with worldwide 2005 sales of over \$6 billion. Plavix is the top-selling drug for Bristol-Myers, whose sales account for approximately 30% of its earning per share.

4. Like most drugs, Plavix eventually goes off patent and is subject to generic competition. The result is that the primary manufacturer will lose substantial revenues because most third party payors will insist that patients switch to the less expensive generic, assuming it is bioequivalent to the non-generic version. By all accounts, Apotex's generic is the bioequivalent to Plavix in all material aspects.

5. Initially, Bristol-Myers was protective of the Plavix patent and took an aggressive posture and threatened litigation against Apotex. In fact, the Company filed a patent infringement lawsuit against Apotex in the United States District Court for the Southern District of New York on March 21, 2002. However, on March 17, 2006, Bristol-Myers and Sanofi negotiated a settlement of the Plavix patent litigation with Apotex (the "Apotex Agreement"), purportedly fearing a finding of patent invalidity and losing their ability to keep generic competition out of the market for Plavix.

6. The Company, however, failed to disclose that Bristol-Myers relinquished material legal rights in order to induce the patent litigation settlement with Apotex, and negotiated improper side-agreements with Apotex in order to induce settlement.

7. Moreover, the Company failed to disclose that its upper management team's entry into these side-agreements, like the Apotex Agreement, exposed Bristol-Myers to serious criminal charges and liability from class action lawsuits, in addition to heightened regulatory scrutiny. Furthermore, members of Bristol-Myers' management failed to disclose that senior executives of the Company made criminally false statements in connection with the FDA's review of the Apotex Agreement.

8. Although the precise terms of the Apotex Agreement were not disclosed at the time, it was later reported that in a secret side-agreement Bristol-Myers and Sanofi agreed to pay

Apotex an estimated *\$60 million fee*, and Apotex agreed not to enter the market with its generic version until some time in 2011 – which was only several months before the expected expiration of the Plavix patent. In addition, the Company agreed to forego treble damages if it prevailed in the patent litigation against Apotex, and it agreed not to seek an injunction prohibiting Apotex from selling its then-existing inventory of generic Plavix.

9. Director Defendants knew, or in the exercise of their ordinary duties should have known, that the Apotex Agreement was nothing more than a naked restraint of trade among horizontal competitors that violated both federal and state antitrust regulations.

10. The impropriety of this “pay-not-to-play” deal was first recognized on or about May 5, 2006, when the Federal Trade Commission (“FTC”), in lieu of rejection, told Bristol-Myers to withdraw the first incarnation of the Apotex Agreement because of several objectionable provisions. The Company was required to submit the Apotex Agreement to the FTC pursuant to a consent decree entered into by Bristol-Myers and the FTC, which limited Bristol-Myers’ ability to enter into agreements delaying competitors from marketing generic versions of its drugs because Bristol-Myers had violated antitrust rules on prior occasions (discussed below) (the “FTC Consent Order”).

11. The Apotex Agreement’s continued impropriety was again recognized towards the end of July 2006, when it was rejected by all 50 state attorneys general who said it still did not comply with the FTC Consent Order.

12. On July 28, 2006, it was reported that the Antitrust Division of the DOJ was investigating allegations that Bristol-Myers deceived federal antitrust enforcers about the events surrounding the rejected Apotex Agreement. Reportedly, the FTC, which was reviewing the proposed Apotex Agreement, requested that a criminal investigation begin after officials at

Apotex contradicted statements Bristol-Myers made to the FTC.

13. As part of this on-going criminal investigation into to the Apotex Agreement, two day earlier, on July 26, 2006, agents for the DOJ and the Federal Bureau of Investigation ("FBI") raided Bristol-Myers' New York City offices, including the office of its former Chief Executive Officer ("CEO"), Peter R. Dolan, for documents and emails that might provide evidence to support the FTC complaint.

14. The DOJ investigation was not premised on the formal publicly announced Apotex Agreement, rather upon information and belief, it arises out of the secret side-agreement between Apotex and Bristol-Myers, which provided that Bristol-Myers would pay Apotex a secret \$60 million fee so it would delay launching its generic until 2011, in addition to reinforcing the provision giving Apotex a six-month head-start to introduce the generic version before Bristol-Myers or any other manufacturers could launch their generic versions of Plavix.

15. On August 8, 2006, Bristol-Myers revealed that it had substantially modified its settlement agreement with Apotex to the Company's detriment. Bristol-Myers admitted that it had waived its right to seek treble damages in the patent litigation, and also had agreed not to seek a temporary restraining order or a preliminary injunction against Apotex's launch of its generic Plavix drug.

16. Subsequently, Bristol-Myers terminated its CEO and General Counsel for their roles in the negotiation of the settlement agreement with Apotex – though these Board actions came after the damage had already been done.

17. To resolve the criminal investigation by the DOJ, in May 2007, Bristol-Myers pleaded guilty to two violations of the federal False Statements Act for making false statements to the FDA in connection with the settlement negotiations and subsequent agreement with

Apotex. The Company also paid the maximum permissible criminal fine, in the amount of \$1 million.

18. Director Defendants engaged in illegal conduct designed to circumvent the antitrust laws and avoid Bristol-Myers' compliance with the FTC Consent Order with respect to generic competition. Director Defendants should have taken steps to prevent its former CEO, Mr. Dolan, and his lieutenants, from negotiating and then trying to follow through on a deal – the Apotex Agreement – that was on its face a violation of law and violated the FTC Consent Order. This is especially egregious given the Company's well-documented history of anti-competitive conduct when dealing with generic competition. The Bristol-Myers Board's failure to actively oversee events at the Company has, in part, left Bristol-Myers exposed to criminal and regulatory sanctions, severe harm to its reputation, and a massive market capitalization decline.

19. Accordingly, Plaintiff, derivatively on behalf of Bristol-Myers, seeks relief for the damages sustained, and to be sustained, by Bristol-Myers as a result of Director Defendants' breaches of the duty of care and fiduciary duty. As alleged herein, these breaches caused Bristol-Myers to be sued for, and exposed to liability for, violations under the anti-trust and anti-fraud laws, exposed Bristol-Myers to criminal and regulatory sanctions, and damaged the Company's reputation and goodwill.

#### **JURISDICTION AND VENUE**

20. This Court has jurisdiction over all claims asserted herein pursuant to 28 U.S.C. § 1332, as the parties are citizens of different states and the amount in controversy in this matter exceeds \$75,000, exclusive of interest and costs.

21. This action is not a collusive action designed to confer jurisdiction on a court of the United States that it would not otherwise have.

22. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(a)(1), because one or more of Defendants either resides or maintains executive offices in this Judicial District, and a substantial portion of the acts and transactions constituting the violations of law alleged in this Complaint occurred in substantial part in this Judicial District. Moreover, Defendants have received compensation in this Judicial District by doing business here and engaging in numerous activities that had an effect in this Judicial District.

### **THE PARTIES**

#### **The Plaintiff**

23. Plaintiff Steven W. Sampson, Trustee, is a resident of Florida and has owned at times relevant to this action, and continues to own, Bristol-Myers common stock.

#### **The Nominal Defendant**

24. Nominal Defendant Bristol-Myers is incorporated in the state of Delaware and maintains its principal executive office in this County at 345 Park Avenue, New York, New York 10154. Bristol-Myers common stock trades and has traded on the New York Stock Exchange under the symbol "BMY." The Company engages in the discovery, development, licensing, manufacture, marketing, distribution, and sale of pharmaceutical and other health care products in the United States and internationally.

#### **The Director Defendants**

25. The following parties, sometimes referred to herein as the "Director Defendants," during the relevant time period, served as members of the Board of Directors of Bristol-Myers as follows:

#### **James D. Robinson III**

26. Director Defendant James D. Robinson III is a citizen of New York. He has served as a director of Bristol-Myers since 1976, and since June 12, 2005, Mr. Robinson has



served as the Chairman of the Board. He serves as a member, *ex-officio*, of all Board committees, which include: (1) the Audit Committee; (2) the Compensation and Management Development Committee; (3) the Committee on Directors and Corporate Governance; and (4) the Science and Technology Committee. Moreover, in November 2006, the Bristol-Myers Board established a Securities Issuance Committee to determine and approve the terms and provisions of securities issued by the Company in the fourth quarter of 2006. Following the completion of its responsibilities, the Securities Issuance Committee was dissolved on December 31, 2006. Mr. Robinson served as a member of this Committee. In addition, Mr. Robinson is Co-founder and General Partner of RRE Ventures, a private information technology venture investment firm, since 1994. He previously served as Chairman and CEO of American Express Company, a financial services company, from 1977 to 1993, and is also a director of Novell, Inc., The Coca-Cola Company and First Data Corporation. Mr. Robinson is a member of The Business Council, the Council on Foreign Relations, and the Committee for Economic Development. For serving in his Bristol-Myers capacities, upon information and belief, Mr. Robinson was paid \$286,583, which combined the annual \$45,000 non-management directors' retainer with a prorated non-executive Chairman retainer, for fiscal year ending December 31, 2005.

27. As Chairman of the Board, Mr. Robinson owed a duty to Bristol-Myers and its shareholders to be reasonably informed about the business, operations, and finances of the Company. Rather than fulfill these important fiduciary duties Mr. Robinson owed to Bristol-Myers, he actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts complained of herein, and/or breached his fiduciary duties to Bristol-Myers and its shareholders by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Because of Mr. Robinson's positions, he knew the adverse non-public information

about the business of Bristol-Myers, as well as its finances, markets and accounting practices, via access to internal corporate documents, conversations and connections with other corporate directors, officers, and employees, attendance at Board meetings and committees thereof, and via reports and other information provided to him in connection therewith.

Lewis B. Campbell

28. Director Defendant Lewis B. Campbell has served as a director of Bristol-Myers since 1998. Mr. Campbell is currently registered to vote in three states, and until a few months ago was a citizen of Michigan. On information and belief, Mr. Campbell now resides in and is a citizen of Rhode Island. Mr. Campbell is Chairman of Bristol-Myers' Compensation and Management Development Committee, and a member of both the Company's Audit Committee and Committee on Directors and Corporate Governance. Since February 1999, he has been Chairman, President and CEO of Textron Inc., a multi-industry company based in Providence, Rhode Island, serving the aircraft, fastening systems, industrial products and components, and financial industries. Mr. Campbell is also a director of Dow Jones & Company. Mr. Campbell is a member of the G 100 Group, The Business Council, The Business Roundtable, and the Defense Industry Initiative Steering Committee. For serving in his Bristol-Myers capacities, upon information and belief, Mr. Campbell was paid \$120,417, which included the annual \$45,000 non-management directors' retainer, for fiscal year ending December 31, 2005.

29. As a member of the Board, Mr. Campbell owed a duty to Bristol-Myers and its shareholders to be reasonably informed about the business, operations, and finances of the Company. Rather than fulfill these important fiduciary duties Mr. Campbell owed to Bristol-Myers, he actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts complained of herein, and/or breached his fiduciary duties to Bristol-Myers and its shareholders by purposefully, recklessly and/or negligently disregarding these wrongful acts or

omissions. Because of Mr. Campbell's positions, he knew the adverse non-public information about the business of Bristol-Myers, as well as its finances, markets and accounting practices, via access to internal corporate documents, conversations and connections with other corporate directors, officers, and employees, attendance at Board meetings and committees thereof, and via reports and other information provided to him in connection therewith.

James M. Cornelius

30. Director Defendant James M. Cornelius is, on information and belief, a citizen of Indiana. He has served as a director of Bristol-Myers since 2005. Mr. Cornelius was elected CEO of Bristol-Myers on April 30, 2007, after serving as interim CEO since September 12, 2006. In its 2007 Proxy Statement filed with the SEC on Form DEF-14A, the Bristol-Myers Board determined that Mr. Cornelius qualified as an "audit committee financial expert" under the applicable SEC rules. Moreover, Mr. Cornelius had served on the aforementioned Securities Issuance Committee, together with Mr. Robinson. In addition, effective November 15, 2005, Mr. Cornelius became Chairman Emeritus of Guidant Corporation, a U.S. cardiac and vascular medical device company, as the Company is being acquired. Previously, Mr. Cornelius served as Chairman of the Board (Non-Executive) since 2000. From 1995 until 2000, Mr. Cornelius served as the Senior Executive and Chairman of Guidant Corporation. From 1983 to 1994, Mr. Cornelius was a Director, a member of the Executive Committee and Chief Financial Officer of Eli Lilly and Company. Mr. Cornelius is also a director of The Chubb Corporation, The DirecTV Group, Inc., and Given Imaging, Ltd. He is a Managing Partner at Twilight Ventures Partners and a Board member of Leerink Swann & Company and a member of The National Bank of Indianapolis. He serves as Board Trustee and Treasurer of the Indianapolis Museum of Art. For serving in his Bristol-Myers capacities, upon information and belief, Mr. Cornelius was paid \$101,000, which included the annual \$45,000 non-management directors' retainer, for fiscal

year ending December 31, 2005.

31. As a member of the Board, Mr. Cornelius owed a duty to Bristol-Myers and its shareholders to be reasonably informed about the business, operations, and finances of the Company. Rather than fulfill these important fiduciary duties Mr. Cornelius owed to Bristol-Myers, he actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts complained of herein, and/or breached his fiduciary duties to Bristol-Myers and its shareholders by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Because of Mr. Cornelius' positions, he knew the adverse non-public information about the business of Bristol-Myers, as well as its finances, markets and accounting practices, via access to internal corporate documents, conversations and connections with other corporate directors, officers, and employees, attendance at Board meetings and committees thereof, and via reports and other information provided to him in connection therewith.

Laurie H. Glimcher, M.D

32. Director Defendant Laurie H. Glimcher, M.D. is a citizen of Massachusetts. She has served as a director of Bristol-Myers since 1997. Dr. Glimcher is a member of both the Company's Audit Committee and Committee on Directors and Corporate Governance. She is Chairperson of Bristol-Myers' Science and Technology Committee. Dr. Glimcher is an Irene Heinz Given Professor of Immunology at the Harvard School of Public Health and Professor of Medicine at Harvard Medical School since 1991. Dr. Glimcher is also a director of Waters Corporation. She is a Fellow of the American Academy of Arts and Sciences and a member of the National Academy of Sciences and the Institutes of Medicine of the National Academy of Sciences and the Irvington Institute Fellowship Committee. For serving in her Bristol-Myers capacities, upon information and belief, Dr. Glimcher was paid \$107,000, which included the annual \$45,000 non-management directors' retainer, for fiscal year ending December 31, 2005.

33. As a member of the Board, Dr. Glimcher owed a duty to Bristol-Myers and its shareholders to be reasonably informed about the business, operations, and finances of the Company. Rather than fulfill these important fiduciary duties Dr. Glimcher owed to Bristol-Myers, she actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts complained of herein, and/or breached her fiduciary duties to Bristol-Myers and its shareholders by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Because of Dr. Glimcher's positions, she knew the adverse non-public information about the business of Bristol-Myers, as well as its finances, markets and accounting practices, via access to internal corporate documents, conversations and connections with other corporate directors, officers, and employees, attendance at Board meetings and committees thereof, and via reports and other information provided to her in connection therewith.

Vicki L. Sato, Ph.D.

34. Director Defendant Vicki L. Sato, Ph.D. is a citizen of Massachusetts. She has served as a director of Bristol-Myers since July 11, 2006, and is a member of the Company's Science and Technology Committee. Dr. Sato is currently a Professor of Management Practice at the Harvard Business School and a Professor of Molecular and Cell Biology at Harvard University. In 2005, she retired as President of Vertex Pharmaceuticals. Dr. Sato also served as chief scientific officer, senior vice president of research and development, and chair of the Scientific Advisory Board at Vertex before being named president in 2000. Prior to joining Vertex, Dr. Sato was vice president of research at Biogen, Inc. and served on the Biogen Scientific Board. Dr. Sato is also a member of the Board of Directors of PerkinElmer Corporation, Infinity Pharmaceuticals, and Alnylam Pharmaceuticals.

35. As a member of the Board, Dr. Sato owed a duty to Bristol-Myers and its shareholders to be reasonably informed about the business, operations, and finances of the

Company. Rather than fulfill these important fiduciary duties Dr. Sato owed to Bristol-Myers, she actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts complained of herein, and/or breached her fiduciary duties to Bristol-Myers and its shareholders by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Because of Dr. Sato's positions, she knew the adverse non-public information about the business of Bristol-Myers, as well as its finances, markets and accounting practices, via access to internal corporate documents, conversations and connections with other corporate directors, officers, and employees, attendance at Board meetings and committees thereof, and via reports and other information provided to her in connection therewith.

Leif Johansson

36. Director Defendant Leif Johansson is a citizen of Sweden. He has served as a director of Bristol-Myers since 1998. Mr. Johansson is a member of both the Company's Audit Committee and Committee on Directors and Corporate Governance. He is President of AB Volvo, an automotive company and CEO of The Volvo Group since 1997. Mr. Johansson is Chairman of the Board of ACEA, Commercial Vehicles as well as a director of The Confederation of Swedish Enterprise, Royal Swedish Academy of Engineering Sciences, the Association of Swedish Engineering Industries, and the Association des Constructeurs Europeens d'Automobiles. He is also a member of the European Business Roundtable of Industrialists. For serving in his Bristol-Myers capacities, upon information and belief, Mr. Johansson was paid \$103,000, which included the annual \$45,000 non-management directors' retainer, for fiscal year ending December 31, 2005.

37. As a member of the Board, Mr. Johansson owed a duty to Bristol-Myers and its shareholders to be reasonably informed about the business, operations, and finances of the Company. Rather than fulfill these important fiduciary duties Mr. Johansson owed to Bristol-



Myers, he actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts complained of herein, and/or breached his fiduciary duties to Bristol-Myers and its shareholders by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Because of Mr. Johansson's positions, he knew the adverse non-public information about the business of Bristol-Myers, as well as its finances, markets and accounting practices, via access to internal corporate documents, conversations and connections with other corporate directors, officers, and employees, attendance at Board meetings and committees thereof, and via reports and other information provided to him in connection therewith.

Louis J. Freeh

38. Director Defendant Louis J. Freeh is, on information and belief, a citizen of Virginia. He has served as a director of Bristol-Myers since 2005. Mr. Freeh is a member of both the Company's Audit Committee and Committee on Directors and Corporate Governance. He served as Vice Chairman, General Counsel, Corporate Secretary and Ethics Officer to MBNA Corporation from 2001 until its acquisition by Bank of America in January 2006. Mr. Freeh also served as FBI Director from 1993 to 2001 and previously as a U.S. District Judge, Assistant U.S. Attorney, and FBI Special Agent. He is also a director of L-1 Identity Solutions, Inc.

39. As a member of the Board, Mr. Freeh owed a duty to Bristol-Myers and its shareholders to be reasonably informed about the business, operations, and finances of the Company. Rather than fulfill these important fiduciary duties Mr. Freeh owed to Bristol-Myers, he actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts complained of herein, and/or breached his fiduciary duties to Bristol-Myers and its shareholders by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Because of Mr. Freeh's positions, he knew the adverse non-public information about

the business of Bristol-Myers, as well as its finances, markets and accounting practices, via access to internal corporate documents, conversations and connections with other corporate directors, officers, and employees, attendance at Board meetings and committees thereof, and via reports and other information provided to him in connection therewith.

Michael Grobstein

40. Director Defendant Michael Grobstein is a citizen of New York. He has served as a director of Bristol-Myers since March 2007. Mr. Grobstein is a member of the Company's Audit Committee. In its 2007 Proxy Statement filed with the SEC on Form DEF-14A, the Bristol-Myers Board determined that Mr. Grobstein qualified as an "audit committee financial expert" under the applicable SEC rules. He is also Retired Vice Chairman of Ernst & Young LLP. Mr. Grobstein is also a director of Given Imaging Ltd. and serves on the Board of Trustees and Executive Committee of the Central Park Conservancy and on the Board of Directors of New Yorkers for Parks.

41. As a member of the Board, Mr. Grobstein owed a duty to Bristol-Myers and its shareholders to be reasonably informed about the business, operations, and finances of the Company. Rather than fulfill these important fiduciary duties Mr. Grobstein owed to Bristol-Myers, he has done nothing substantively to remedy the Company's injuries caused by the malfeasance described herein, and/or breached his fiduciary duties to Bristol-Myers and its shareholders by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Because of Mr. Grobstein's positions, he knew the adverse non-public information about the business of Bristol-Myers, as well as its finances, markets and accounting practices, via access to internal corporate documents, conversations and connections with other corporate directors, officers, and employees, attendance at Board meetings and committees thereof, and via reports and other information provided to him in connection therewith.



R. Sanders Williams, M.D.

42. Director Defendant R. Sanders Williams, M.D. is a citizen of North Carolina. He has served as a director of Bristol-Myers since September 11, 2006, and is a member of the Company's Science and Technology Committee. Dr. Williams is Senior Vice Chancellor for Academic Affairs at Duke University Medical Center since 2007 and Dean of Duke University School of Medicine since 2001. He serves on the Director's Advisory Committee of the National Institutes of Health and the Board of External Advisors to the National Heart, Lung and Blood Institute, and is also a member of the Institutes of Medicine of the National Academy of Sciences and a fellow of the American Association for the Advancement of Science.

43. As a member of the Board, Dr. Williams owed a duty to Bristol-Myers and its shareholders to be reasonably informed about the business, operations, and finances of the Company. Rather than fulfill these important fiduciary duties Dr. Williams owed to Bristol-Myers, he has done nothing substantively to remedy the Company's injuries caused by the malfeasance described herein, and/or breached his fiduciary duties to Bristol-Myers and its shareholders by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Because of Dr. Williams' positions, he knew the adverse non-public information about the business of Bristol-Myers, as well as its finances, markets and accounting practices, via access to internal corporate documents, conversations and connections with other corporate directors, officers, and employees, attendance at Board meetings and committees thereof, and via reports and other information provided to him in connection therewith.

Additional Relevant Non-Defendant Individuals

Peter R. Dolan

44. Former Director Peter R. Dolan served as Bristol-Myers' CEO in May 2001, until September 12, 2006, one day after a federal monitor recommended that he be fired. Mr. Dolan

had also served as a director of the Company since 2000, until his resignation from the Board in September 2006. Mr. Dolan was Chairman of the Bristol-Myers Board from September 2001 to June 2005.

Robert E. Allen

45. Former director Robert E. Allen served as a director of Bristol-Myers since 1986, until his retirement from the Board on March 22, 2007. Mr. Allen was, at relevant times, Chairman of Bristol-Myers' Directors and Corporate Governance Committee, and a member of the Company's Audit Committee and Executive Committee.

Vance D. Coffman

46. Former director Vance D. Coffman served as a director of Bristol-Myers since 1998, until his retirement from the Board on March 22, 2007. Mr. Coffman was, at relevant times, Chairman of Bristol-Myers' Audit Committee, and a member of the Company's Compensation and Management Development Committee.

Dr. Andrew G. Bodnar

47. Former Bristol-Myers employee, Dr. Andrew G. Bodnar, was Senior Vice President of Strategy and Medical & External Affairs, as well as a Corporate Staff Member of the Company's Executive Committee. Dr. Bodnar, upon information and belief, is believed to be "BMS Executive-1" (discussed below).

Bernard C. Sherman

48. Bernard C. Sherman is chief executive of Apotex and owner of the privately held company. Mr. Sherman, upon information and belief, is believed to be "Apotex Executive-1" (discussed below).

**Additional Relevant Non-Defendant Entities**

**Sanofi-Aventis**

49. Sanofi is a French corporation headquartered in Paris, France and maintains a domestic headquarters in Bridgewater, New Jersey. Sanofi is the third largest pharmaceutical manufacturer in the world, and develops, manufactures, and sells brand-name pharmaceutical products throughout the United States and elsewhere. Sanofi jointly markets Plavix with Bristol-Myers.

**Apotex Corporation**

50. Apotex is a private corporation that is incorporated in the state of Delaware and maintains its principal executive office at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Apotex is a wholly-owned subsidiary of Apotex, Inc., Canada's largest generic drug manufacturer, with more than 260 generic pharmaceutical products in approximately 4000 dosages and formats, distributed worldwide. Apotex developed a generic version of Plavix.

**OBLIGATIONS OF DIRECTOR DEFENDANTS**

51. Each of the Director Defendants owed to Bristol-Myers the duty to exercise due care and diligence in the management and administration of the affairs of the Company and in the use and preservation of its property and assets, and owed the duty of full and candid disclosure of all material facts related thereto. Further, Director Defendants owed a duty to Bristol-Myers and its shareholders to ensure that Bristol-Myers operated in compliance with all applicable federal and state laws, rules, and regulations; and that Bristol-Myers did not engage in any unsafe, unsound, or illegal business practices.

52. To discharge these duties, Director Defendants were required to exercise reasonable and prudent supervision over the management, policies, practices, controls, and financial and corporate affairs of Bristol-Myers. By virtue of this obligation of due care and

diligence, Director Defendants were required, among other things, to:

- (a) manage, conduct, supervise, and direct the employees, businesses and affairs of Bristol-Myers in accordance with laws, rules and regulations, and the charter and by-laws of Bristol-Myers;
- (b) neither violate nor knowingly or recklessly permit any officer, director or employee of Bristol-Myers to violate applicable laws, rules and regulations and to exercise reasonable control and supervision over such officers and employees; ensure the prudence and soundness of policies and practices undertaken or proposed to be undertaken by Bristol-Myers;
- (c) remain informed as to how Bristol-Myers was, in fact, operating, and upon receiving notice or information of unsafe, imprudent or unsound practices, to make reasonable investigation in connection therewith and to take steps to correct that condition or practice;
- (d) supervise the preparation, filing and/or dissemination of any SEC filing, press releases, audits, reports or other information disseminated by Bristol-Myers and to examine and evaluate any reports of examinations or investigations concerning the practices, products or conduct of officers of Bristol-Myers and to make full and accurate disclosure of all material facts, concerning *inter alia*, each of the subjects and duties set forth above; and
- (e) preserve and enhance Bristol-Myers's reputation as befits a public corporation and to maintain public trust and confidence in Bristol-Myers as a prudently managed institution fully capable of meeting its duties and obligations.

## **BACKGROUND**

### **The Regulatory Structure Pursuant To Which Generic Substitutes For Brand-Name Drugs Are Approved**

53. Under the Federal Food, Drug, and Cosmetics Act (21 U.S.C. §§ 301-392), manufacturers who create a new drug must obtain the approval of the U.S. Food and Drug Administration ("FDA") to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include the submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

54. In 1984, Congress amended the Food, Drug and Cosmetics Act with the enactment of the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), otherwise known as the Hatch-Waxman amendments ("Hatch-Waxman").

55. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need to file a lengthy and costly NDA to obtain FDA approval. The FDA instead provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA") assuming certain criteria are satisfied.

56. The ANDA references and relies upon the scientific findings of safety and effectiveness included by the brand-name drug manufacturer in the original NDA. The ANDA filer must demonstrate to the FDA that the generic drug it is taking to market is at least bioequivalent to the referenced brand-name drug.

57. Generic drugs are drugs that the FDA has found to be "bioequivalent" to their corresponding brand name drug. A generic drug is bioequivalent if it provides the identical therapeutic benefits, and it has the same active chemical composition as its brand name counterpart. When a generic drug is completely equivalent to a pioneer or brand name drug, the FDA assigns the generic drug an "AB" rating.

58. Generic drugs are invariably priced substantially below the branded drugs to which they are bioequivalent. Typically, the first generic drug is sold at a modest discount compared to the brand name drug, with discounts increasing, as per normal competitive dynamics, as more companies begin selling the generic. As additional generic competitors come to market, the price of the generic equivalents continues to fall, and the combined market share of the generic manufacturers continues to grow. In some cases, generic competitors sell products equivalent to brand name prescription drugs for as little as 15 percent of the price of the brand name drug, and capture as much as 90 percent of the market for that drug in very short order. Specifically, unless the branded manufacturer lowers prices to meet competition, a branded drug loses a significant portion of its market share to generic competitors less than a year after the introduction of generic competition.

59. Hatch-Waxman also streamlined the process for a brand-name manufacturer to enforce its patents against generic manufacturers, and provided the brand-name manufacturer with what is essentially a self-executing preliminary injunction against generic competition, in the form of an automatic stay of FDA approval of the ANDA that may last as long as thirty months.

60. Under Hatch-Waxman, the NDA holder submits a list of patents, if any, that "claim[] the drug for which the applicant submitted the application or which claim[] a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). Under FDA regulations, the only types of patents that can be submitted by the NDA filer are drug substance patents, drug product patents and method of use patents. Drug product patents may be submitted only if they claim "a drug product that is the

subject of a pending or approved application.” Drug substance patents may be submitted only if they claim “a drug substance that is a component of [the drug product that is the subject of the NDA].” Method of use patents may be submitted only if they claim an approved (or pending) use of the drug product.

61. When the FDA approves a brand-name manufacturer’s NDA, the FDA publishes the patents, if any, submitted by the NDA filer in a publication entitled the “Approved Drug Products with Therapeutic Equivalence Evaluations,” known as the “Orange Book.” 21 U.S.C. §355(j)(7)(A)(iii). In listing patents in the Orange Book, the FDA merely performs a ministerial act. The FDA does not check the facts supplied to it by the brand-name manufacturer, but trusts that the manufacturer will be truthful. The FDA does, however, require that the NDA holder submit a certification attesting to the propriety of the Orange Book listing. After the NDA is approved, the brand-name manufacturer may list other newly-issued patents in the Orange Book under the NDA, if the brand-name manufacturer similarly certifies, *inter alia*, that the new patents claim either the approved (or pending) drug product, a drug substance in that drug product, or an approved (or pending) method of using that drug product.

62. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications: (1) that no patent for the brand-name drug has been filed with the FDA (a “Paragraph I Certification”); (2) that the patent for the brand-name drug has expired (a “Paragraph II Certification”); (3) that the patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a “Paragraph III Certification”); or (4) that the patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a “Paragraph IV Certification”). 21 U.S.C. §355(j)(2)(A)(vii).



63. To obtain FDA approval of an ANDA (and thus the legal right to sell a generic version of a brand-name drug) prior to the expiration of a patent listed in the Orange Book for the referenced NDA, a generic manufacturer must certify that the generic drug addressed in its ANDA does not infringe any valid claim in that patent (*i.e.*, file a Paragraph IV Certification).

64. If a generic manufacturer files a Paragraph IV Certification asserting that the patent is invalid or will not be infringed, then the brand-name manufacturer has the opportunity to delay the generic manufacturer's receipt of final FDA approval, and thus, its ability to come to market. This is because a generic manufacturer filing a Paragraph IV Certification must promptly give notice of its ANDA Certification to both the NDA owner and the owner of the patent(s) at issue. The generic manufacturer's act of filing a Paragraph IV Certification triggers the time by which a patent owner may file an action for patent infringement, and take advantage of the self-executing stay of FDA's ability to finally approve the generic version of the NDA owner's drug.

65. If the patent owner fails to initiate a patent infringement action within 45 days after receiving the generic manufacturer's Paragraph IV Certification, then the FDA may grant final approval to the generic manufacturer's ANDA once it concludes that the generic is bioequivalent to the brand-name drug. If, however, the patent owner initiates an infringement action against the ANDA filer within 45 days, then the FDA may not finally approve the ANDA until the earlier of either 30 months or the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. §355(j)(5)(B)(iii).

66. Additionally, the Hatch-Waxman statutory scheme in place at all relevant times provided a 180-day period of market exclusivity to the first generic manufacturer that filed an ANDA containing a Paragraph IV Certification, commencing on the date the generic



manufacturer began marketing the new drug or, if there was a patent infringement claim against it, from the date the generic manufacturer received a patent infringement decision in its favor, whichever was earlier. If neither of these conditions occurred, the exclusivity period would not expire and no other generic manufacturer could market its generic version of the affected drug.

67. Typically, generic versions of brand-name drugs are initially priced significantly below their corresponding brands. As a result, direct purchasers substitute generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers. Moreover, the brand-name drug continues to lose market share to the generics. This price competition enables direct purchasers of the drugs to: (a) purchase generic versions of a drug in substitution for the brand at lower prices and/or (b) purchase the brand-name drug at reduced prices. Consequently, brand-name drug manufacturers have a substantial and compelling financial interest in delaying generic competition.

### **SUBSTANTIVE ALLEGATIONS**

#### **The Plavix Patent**

68. Bristol-Myers and Sanofi jointly market Plavix, a brand-name prescription blood thinner used to ward off stroke and heart attack. The active ingredient in Plavix is clopidogrel bisulfate, the hydrogen sulfate salt of clopidogrel.

69. Sanofi submitted an NDA for Plavix tablets, 75 mg, on April 28, 1997. On November 17, 1997, the FDA approved Sanofi's NDA. Bristol-Myers then began selling Plavix throughout the United States pursuant to its business partnership with Sanofi.

70. On November 16, 2001, Apotex filed an ANDA seeking FDA approval to market a generic version of Plavix in the United States. Apotex was the first generic applicant to seek such approval. In connection with its ANDA, Apotex submitted a Paragraph IV Certification

stating that each patent listed in the Orange Book for Plavix was invalid, unenforceable or would not be infringed by Apotex's proposed generic product. Apotex notified Sanofi of its Paragraph IV Certification with respect to these patents.

71. Shortly thereafter, on March 21, 2002, Bristol-Myers and Sanofi commenced the Plavix patent litigation -- a patent infringement action against Apotex under 35 U.S.C. § 271(e)(2)(A), in the Southern District of New York, triggering a 30-month delay in FDA approval of Apotex's ANDA. As originally filed, the Plavix patent litigation alleged Apotex's infringement of both the '265 patent and the '328 patent. Subsequently, the claim for infringement of the latter patent was withdrawn, with prejudice, leaving only the claim for infringement of the '265 patent.

72. The Plavix patent infringement litigation was set for trial in April 2006.

73. By late 2005, Apotex was aware that FDA approval of its ANDA was imminent and began preparing to launch generic Plavix as soon as it received that approval. At that time, Apotex contacted its customers to obtain pre-launch commitments and purchase orders for generic Plavix. Apotex stated that it intended to launch upon receipt of FDA approval and was not concerned about launching generic Plavix "at-risk," even though it knew that in the event that Bristol-Myers and Sanofi won the Plavix patent litigation it would be liable for treble damages.

74. On January 20, 2006, Apotex received final FDA approval to market its generic version of Plavix. The FDA also advised Apotex that it had been the first to file an ANDA for generic Plavix and was entitled to 180 days of marketing exclusivity that would begin to run from the earlier of commercial marketing by Apotex or the dates of certain court decisions identified in the Hatch-Waxman Act.

75. On this same day, January 20, 2006, Apotex issued a press release announcing its receipt of FDA approval. Further, Apotex's press release stated that it was confident that Bristol-Myers' and Sanofi's '265 patent would be found invalid in the upcoming Plavix patent litigation.

76. Bristol-Myers and Sanofi were aware that Apotex had received final FDA approval and either knew or suspected that Apotex intended to launch "at-risk." Bristol-Myers and Sanofi were concerned about this because of the large contribution Plavix made to their profits. Bristol-Myers and Sanofi could have asked the district court in New York to issue a preliminary injunction maintaining the status quo until the Plavix patent litigation was resolved, but did not do so.

#### **The Apotex Agreement**

77. Instead of filing a motion for preliminary injunction, Bristol-Myers (and Sanofi) commenced negotiations with Apotex. This was a calculated effort by the Company to have Apotex delay its launch of the generic competition, and, in return, Bristol-Myers would pay Apotex a portion of the profits it would earn as a result of that delay – a "pay-not-to-play" deal. Such an agreement would maintain Bristol-Myers' ability to earn profits by depriving consumers of the benefits of generic competition. Indeed, Bristol-Myers could share a significant portion of its profits with Apotex, and still be far better off than if it faced generic competition from Apotex.

#### **The Initial Apotex Agreement**

78. According to the DOJ's Felony Information, filed on May 30, 2007 (discussed below), in or about January 2006, Bristol-Myers approached Apotex about the possibility of settling the Plavix patent litigation, which was then scheduled for trial in April 2006.

79. Bristol-Myers and Apotex negotiated the terms of the initial Plavix patent

settlement agreement from January to March 2006 (the “initial Apotex Agreement”). During the negotiations, Apotex insisted Bristol-Myers commit *not* to launch an authorized generic during the period of any license granted to Apotex.

80. On March 17, 2006, Bristol-Myers and Apotex executed the initial Apotex Agreement.

81. On March 21, 2006, after the market closed, Bristol-Myers issued a press release entitled “Sanofi-Aventis and Bristol-Myers Squibb Announce Agreement to Settle U.S. PLAVIX Litigation with Apotex Subject to Certain Conditions.” The press release detailed the terms surrounding the parties’ entry into the initial Apotex Agreement, including Apotex’s agreement not to enter the market with its FDA-approved generic version of Plavix until September 17, 2011, just two months before the scheduled expiration of Bristol-Myers’ ‘265 patent. The initial Apotex Agreement further provided that Bristol-Myers would grant Apotex an exclusive license to sell its generic product that would become effective on September 17, 2011, and that Bristol-Myers would delay launching its own “authorized” generic during Apotex’s 180-day exclusivity period.

82. The press release issued by Bristol-Myers and approved by the Director Defendants on March 21, 2006, did not disclose the size of the payments to Apotex.

83. It was not until August 2006, after the settlement deal with Apotex was effectively dead, that Bristol-Myers disclosed Apotex would receive an estimated **\$60 million** pursuant to a secret side-agreement, even if the Apotex Agreement was not approved by the FTC and the 50 state attorneys general. In these later press releases, Bristol-Myers indicated that the estimated \$60 million payment was a “reimbursement payment from the companies for certain short-dated inventories of Apotex’s clopidogrel bisulfate product.” The “short-dated” inventories

related to some of Apotex's generic Plavix inventory that Apotex was prepared to launch just prior to entering into the Apotex Agreement with Bristol-Myers (discussed below).

84. In the past, Bristol-Myers has been accused of using patents to thwart low-cost rivals for the cancer medicine TAXOL® and anti-anxiety drug BUSPAR®. Because of this prior similar misconduct, in April 2003, the FTC and Bristol-Myers entered into the FTC Consent Order that, among other things, prohibited Bristol-Myers from settling any patent infringement litigation with any generic drug producer without first submitting the settlement agreement to the FTC, who would review it for anti-competitive provisions. The FTC Consent Order is in effect for 10 years, running through 2013. It requires Bristol-Myers to obtain approval from the FTC and all 50 states' attorneys general before it enters into any agreement to settle a patent infringement case.

85. Accordingly, pursuant to the FTC Consent Order, Bristol-Myers was required to submit the initial Apotex Agreement to the FTC and all 50 state attorneys general for approval before it became effective.

86. Apotex therefore consented to the postponement of the Plavix patent litigation's previously set April 2006 trial date until after the FTC and all 50 state attorneys general reviewed the initial Apotex Agreement.

87. If the initial Apotex Agreement was approved, the payment due to Apotex from Bristol-Myers would have been considerably higher. In effect, the payment from Bristol-Myers to Apotex was payment for Apotex's acquiescence to delay its launch of the generic Plavix pending review by the FTC and all 50 state attorneys general.

88. However, on April 4, 2006, according to the DOJ's Felony Information, the FTC met with outside counsel for Bristol-Myers regarding the initial Apotex Agreement. At this

meeting, the FTC objected to three provisions in the initial Apotex Agreement. Specifically, the FTC objected to the provisions: (i) prohibiting Bristol-Myers from launching an authorized generic version of Plavix during the period of Apotex's exclusive license under the initial Apotex Agreement; (ii) requiring that Bristol-Myers make a payment to Apotex of \$60 million if there was a "regulatory denial" (as that term was defined in the Apotex Agreement) on or before June 30, 2006 ("break-up fee provision"); and (iii) requiring that Bristol-Myers compensate Apotex if annualized Plavix sales did not reach specified minimum levels in the three months preceding Apotex's market entry in accordance with the initial Apotex Agreement ("market guarantee provision").

89. On or around May 5, 2006, the FTC informed Bristol-Myers that it was prepared to reject the initial Apotex Agreement because of these three objectionable provisions. But, rather than reject the initial Apotex Agreement, the FTC allowed Bristol-Myers to withdraw it and try to reach a lawful agreement with Apotex.

90. The FTC's repudiation of the initial Apotex Agreement (because it contained objectionable provisions) was a "red flag" that, at a minimum, either put the Bristol-Myers Board on notice or should have triggered an inquiry given the Company's history of anti-competitive conduct and that it was subject to the FTC Consent Order. Once it was apparent that members of management – including, Mr. Dolan – tried to circumvent the FTC, the Bristol-Myers Board was duty-bound to actively participate in the process and forbid Mr. Dolan and his lieutenants from negotiating a subsequent agreement with Apotex, absent the Board's hands-on involvement.

91. Indeed, given the Company's checkered history and problems in this area, the Board was under an affirmative duty to oversee any subsequent incarnations of the initial Apotex Agreement. As evidenced below, the Bristol-Myers Board failed to perform this task.